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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,277	10/31/2003	Bryn Hird	8473MR2	2057

27752 7590 05/02/2007
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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/699,277

Applicant(s)

HIRD ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1-26-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-28 are presented for examination.

Applicants' drawings filed October 31, 2003 and the information disclosure statements filed January 26, 2004 have been received and entered.

Applicants' election filed April 2, 2007 in response to the restriction requirement of March 16, 2007 has been received and entered. The applicants elected the invention described in claims 1-9 (Group I) with traverse.

Applicants' traverse is not deemed persuasive for reasons set forth in the Office action dated March 16, 2007; therefore, the restriction requirement is hereby made Final.

Claims 10-22 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Claims 23-28 will be examined with the elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by DesMarais et al. (5,20,345) of PTO-1449.

DesMarais et al. teach a foam composition comprising an open-celled structure, and teach that HIPE is the preferred foam (see column 3, lines 30-53 and column 5, lines 25-45). Note the cited reference also teaches that the foam has a density in the

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range of 0.01-0.08 g/cm³ (see column 9, lines 49-54), a specific surface area in the range of 0.5-5 m² /g (see column 8, lines 48-52), and a pore volume of 12-100 ml/g (see column 7, lines 40-43). Finally, the cited reference teaches that the foam is formed from styrene monomers having a Tg above 40°C and acrylate monomers having a Tg of 40°C (see column 17, lines 3-43). The density value set forth in claim 2 is in the range of the cited reference.

Clearly, the cited reference teaches every limitation of the instant composition; therefore, the instant composition is unpatentable.

Claims 1-5 are not allowed.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al. (5,750,585) of PTO-1449.

Park et al. teach open-celled foam compositions and methods of orally administering said forms compositions and treating obesity (see column 3, lines 15-25 and column 15, lines 16-32). The cited reference teaches the open-celled foam composition has a density of 0.015-0.7 (see column 7, lines 35-41), thus the reference contemplates a density less than 0.1, as claimed by the applicants.

Clearly, the cited reference teaches every limitation of the instant composition; therefore, the instant composition is unpatentable.

Claims 1-3 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (5,750,585) in view of Niazi (6,251,421).

Park et al. were discussed above supra for the a composition comprising a non-digestible, non-absorbable, open-celled polymeric foam to treat obesity.

The instant invention differs from the cited reference in that the cited reference does not teach the addition of a lipase inhibitor. However, the secondary reference, Niazi, teaches pharmaceutical compositions comprising a lipase inhibitor, specifically orlistat (also known as tetrahydrolipstatin) having the structure claimed in claims 8 and 9, and teaches that the composition reduces fat absorption and can be administered in oral dosage forms for the treatment of obesity and hyperlipidemia (see column 2, line 24 to column 3, line 61). Additionally, Niazi teaches that the composition can be in the form of commercial pack containing a lipase inhibitor and instructions for its use in the treatment of obesity or hyperlipidemia (see column 3, lines 39-44).

Clearly, one skilled in the art would have been obvious at the time the invention was made to include a lipase inhibitor in the drug delivery foam compositions disclosed by Park et al. to device compositions and kits reducing fat absorption and methods for treating obesity and hyperlipidemia, as taught by Niazi. The expected result would have been successful compositions and kits for fat absorption and treatment of obesity. Because of the teachings of Park et al., that open-celled foam compositions can be used oral drug delivery system, and the teachings of Niazi, that lipase inhibitor compositions can be administered in oral dosage forms for reducing fat absorption and treating obesity, one of ordinary skill in the art would have reasonable expectation that the compositions and kits claimed in

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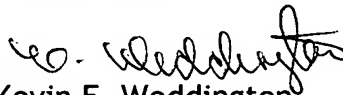
the instant application would be successful in reducing fat absorption and treating obesity. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art the time the invention was made.

Claims 1-9 and 23-28 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kevin E. Weddington
Primary Examiner
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K. Weddington

April 27, 2007